

Study Closure: When & How

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How?

- ❖ **That's the easy part**
- ❖ **Continuing Review in webIRB**
 - **Locate the specific study**
 - **Select “Continuing Review or Closure” in the study workspace**



Current State

Approved

- View Study
- Printer Version
- View Differences
- SS-Print All Request Notes

Owner (IRB Staff):
IRB Staff 1

My Activities

- Send Training Reminder
- Send Inquiry or Reply to IRB
- Study Team - Log Private Comment
- Send Inquiry or Reply to MRSC

New Post-Approval Report or Single Subject Exception

New Amendment

Continuing Review or Closure

Study: Sample Approved Study for webIRB Training - 4

Full Title of Study:	Sample Approved Study for webIRB Training - 4	
Protocol ID:	IRB#11-000045	
Principal Investigator:	A PI4	Study Contact Person:
Faculty Sponsor:		Initial Submission Date:
Review Type:	Full IRB Review	Committee:
Expiration Date:	11/21/2016	Letter of Approval:
PI Proxy:	Rebecca Simms (PI)	
PI Assurances:	Completed	
FS Assurances:	Not Required	

Request to Continue Participants during Approval Lapse:

- History**
- Amendments
- Continuing Review or Closure
- Post-Approval Reports & Single Subject Exception
- Approved Documents
- Completed IRB Requests
- Condition Determination

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How?

❖ CR in webIRB (continued)

- A CR/Closure SmartForm opens
- Question 2.0: pick “Study Closure”

When?

- ❖ For UCLA and where UCLA responsible
- ❖ Study has been approved
- ❖ Enrollment is closed
- ❖ Research interventions complete
- ❖ Follow-up complete
- ❖ No identifiable specimens kept
- ❖ No accessing identifiable data

When?

❖ Sponsored Clinical Trial?

- Sponsor permission
- Close-out visit complete
- Close-out issues resolved
- Source documentation not needed
- Contract/budget issues complete

When?

- ❖ Expired or not
- ❖ Within 30 days

Special Situations

- ❖ Re-opening
- ❖ PI leaves UCLA without closing
- ❖ New safety information

Remember!

- ❖ Re-starting requires approval
- ❖ Record retention period
- ❖ Data confidentiality
- ❖ New safety information
- ❖ Further use of data

Thank you!

❖ For questions:

- **North & South General IRBs**
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